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Dilipkumar Chandubhai Ramolia

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11/12/2008

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EXAMINER

KATAKAM, SUDHAKAR

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/589,999 | RAMOLIA ET AL. | |
| | Examiner | Art Unit | |
| | Sudhakar Katakam | 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/21/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The examiner has considered applicant's Information Disclosure Statement of 8/21/2006. Please refer to the signed copies of the PTO-1449 forms attached herewith.

Claim Objections

2. Claim 14 is objected to because of the following informalities: the letter "I" should be removed from the phrase "where in I step". Appropriate correction is required.
3. Claim 16 is objected to because of the following informalities: unwanted space should be removed from the range "0. 5-4" for the clarity of the sentence. Appropriate correction is required.
4. Claim 18 is objected to because it does not depend on preceding claims.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "highly" in claim 1, line 1, is a relative term, which renders the claim indefinite. The term "highly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is therefore

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impossible to determine the metes and bounds of the claimed subject matter. Claim 1 and its dependents are therefore rendered indefinite.

In claim 1, line 8, the phrases "such as" and "kind such as hereinbefore", renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). It is therefore impossible to determine the metes and bounds of the claimed subject matter. Claim 1 and its dependents are therefore rendered indefinite.

7. The claims 3, 8-11, 13, 15-21 and 24 recite the word "preferable", which renders the claims indefinite for the following reasons:

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "preferable" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 3, 8-11, 13, 15-

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21 and 24 recite the broad recitation, and the claim also recites the narrower statement of the range/limitation.

8. Regarding claim 4, the phrase "like" renders the claim indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

9. Claim 14 recites the limitation "said kinetic resolution" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

10. The term "to get desired" in claims 14-15, is a relative term, which renders the claim indefinite. The term "to get desired" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is therefore impossible to determine the metes and bounds of the claimed subject matter. Claim 14 and its dependents are therefore rendered indefinite.

11. The term "to get optimum results" in claims 17, is a relative term, which renders the claim indefinite. The term "to get optimum results" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is therefore impossible to determine the metes and bounds of the claimed subject matter. Claim 17 and its dependents are therefore rendered indefinite.

12. Claim 22 recites the limitation "kinetically resolved" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

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13. Claim 25 recites the limitation "from I and II purification" in line 2, and during "I purification" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

15. Claims 1-25 are rejected under 35 U.S.C. 102(e) as being anticipated by **Dubey et al** (WO 2004/058694 A1).

Dubey et al disclose a process for the preparation of enantiomerically pure (R) or (S)-5-(2-aminopropyl)-2-methoxybenzenesulfonamide, which comprises the

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resolution of (R,S)- 5-(2-aminopropyl)-2-methoxybenzenesulfonamide with D-(-) or L-(-)-tartaric acid [page 1, lines 4-7]. The process comprises separating the salt by filtration, subjecting the salt kinetic resolution in a solvent system [see Examples], separating the optically pure (R) or (S)-5-(2-aminopropyl)-2-methoxybenzenesulfonamide with optical purity more than 99.5% [see page 4, line 8]. The preferable ratio of (R) or (S)-5-(2-aminopropyl)-2-methoxybenzenesulfonamide to the tartaric acid is 1:1 to 1:1.1 mole [page 4, lines 15-16]. The solvent system preferred is a combination of alcoholic solvents such as methanol, ethanol, propanol having 5-20% (v/v) of polar solvents such as amide solvents, such as dimethylformamide, dimethylsulfoxide or water [page 5, lines 5-7]. The preferable temperature is in between 60-65°C [page 5, lines 11-14]. The reaction time may vary between 4-26 hrs after the addition of amine to the tartaric acid [page 5, lines 15-17]. **Dubey et al** also disclose constant stirring for 1 hour of the reaction mixture and applied cooling to 50°C, maintained for 26 hours and the crystals were collected after filtration and washing [see examples].

Conclusion

16. No Claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/

Examiner, Art Unit 1621

/Daniel M Sullivan/

Supervisory Patent Examiner, Art Unit 1621